

Remarks

Claims

35 USC § 112 ¶ 2 Rejection of Claims 2, 3 and 11

The Office Action rejected Claims 2, 3 and 11 under 35 USC § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 has been amended to more clearly claim the disclosed drug kit. The preamble has been amended to read “A drug kit for cancer gene therapy”. It is now clear that a “drug kit” is being claimed that is to be used for “cancer gene therapy”.

Additionally, Claim 11 has been amended to read “a tumor cell, which is administrated prior to a carrier cell, to perform tumor vaccination”. It is now clear that the “tumor cell” “performs” the “tumor vaccination” and the phrase “which is administrated prior to a carrier cell” describes how the “tumor cell” is to be administered.

The Examiner is requested to withdraw the 35 USC § 112 ¶ 2 rejection of Claims 2, 3, and 11. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2, 3 and 11.

35 USC § 103(a) Rejection of Claims 2, 3 and 11

The Office Action rejected Claims 2, 3 and 11 under 35 USC 103(a) as being unpatentable over Nanni *et al.*, in view of Hamada *et al.* Alternatively, the Office Action rejected Claims 2, 3 and 11 under 35 USC 103(a) as being unpatentable over Nanni *et al.*, in view of Tsukuda *et al.* and Barker *et al.*

Applicants disagree with the conclusion of the Office Action that the cited combinations of references disclose “each and every” feature of Claim 11, and Traverse.

The Office Action merely asserts that A549 cell is disclosed in Hamada and Tsukuda, but never states why it would be “obvious to try” the claimed combination of items in the kit by a person skilled in the art.

The kit in Claim 11 is not just a carrier cell (A549 cell) but a combination of a carrier cell and a tumor cell; and the remarkable result achieved by administering a tumor cell and an adenovirus-infected A549 cell.

Nanni *et al.* does not disclose carrier cells, and Hamada or Tsukuda do not disclose administering a tumor cell to perform tumor vaccination. *KSR* does not allow the mere picking of items from a shopping list disclosed in the application to make a 103 rejection. Although *KSR* may have lowered the standard for citing references for a 103 rejection, *KSR* still requires a showing that it would have been “obvious to try” the claimed combination of items by a person skilled in the art. The Office Action fails to cite any disclosure in the references to support the alleged “obvious to try”.

In *KSR*, the court quoting *In re Kahn* (Fed Cir 2006) (Page 15, second paragraph), stated that “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Therefore, the Examiner is requested to clearly articulate the reason(s) why the claimed “drug kit for cancer gene therapy” would have been obvious to try by a person skilled in the art after reading the cited references.

The Office Action fails to state how a person skilled in the art would know to combine the claimed specific items in a kit to achieve the disclosed superior results. It is only after the disclosure of this application that a person skilled in the art would think of combining Hamada *et al.* or Tsukuda *et al.* with Nanni *et al.* This selection of references in order to obtain the claimed items in the kit has been accomplished by hindsight; which is improper for making a 103 rejection.

Furthermore, even though Hamada and Tsukuda disclose a A549 cell, the main findings of these references is a replication-selective adenovirus for cancer therapy. However, these references do not disclose any reason to combine a A549 cell with a tumor cell.

Additionally, as shown in paragraph [0168] of the present specification and Fig. 22 (a) and (b), tumors completely disappeared in mice by tumor vaccination followed by adenovirus-infected A549 cells. This result is much superior when compared with only administering a carrier cell adenovirus-infected A549 cell. The superior synergetic result due to the combined

use of a tumor cell and a A549 cell (carrier cell) when compared to the use of a carrier cell alone shows unexpected results, which demonstrate the lack of the “obvious to try” standard.

Barker only teaches the IAI.3B promoter and BRACA1 promoter are involved in breast and ovarian cancer, however it does not disclose a carrier cell or tumor vaccination.

Therefore, the kit in Claim 11 is unobvious over Nanni *et al.*, in view of Tsukuda *et al.* and Barker *et al.* Claims 2 and 3 depend from Claim 11 and thus these claims are also unobvious over the cited references.

The Examiner is requested to withdraw Nanni *et al.*, in view of Hamada *et al.*; and Nanni *et al.*, in view of Tsukuda *et al.* and Barker *et al.* as 103(a) references. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2, 3 and 11.

Rejoinder of Claims 4 - 7 and 9

Claims 4 – 7 and 9 are currently withdrawn. As Claim 11 is allowable, as amended, and Claims 4 – 7 contain all the features of the claim from which they depend, the Examiner is respectfully requested to rejoin Claims 4 - 7. In light of the foregoing arguments, the Examiner is respectfully requested to allow Claims 4 – 7 and 9.

